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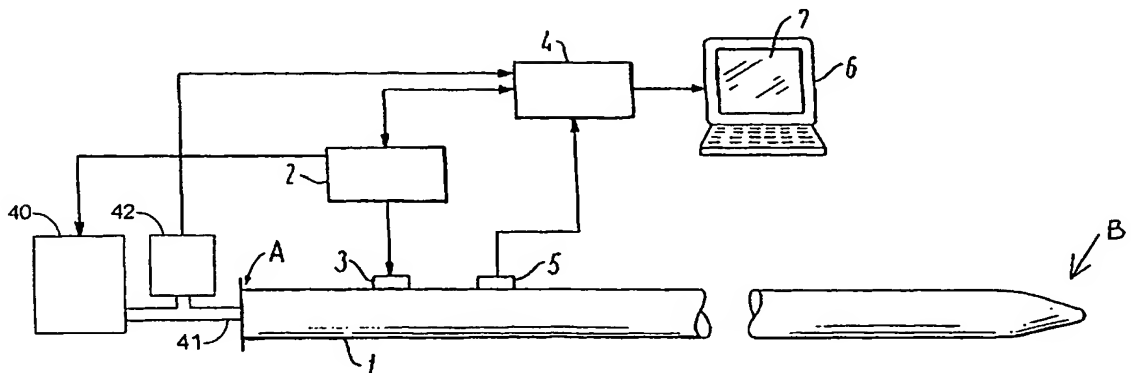
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- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: **DEVICE AND METHOD FOR MEASURING IN BODY CAVITIES**



(57) Abstract: A device comprising a catheter (1) with a lumen, a proximal end (A) and a closed distal end (B) for inserting into the human or animal body cavity. A signal generator (2) generates an excitation signal, and a transmitting transducer (3) transmits a corresponding acoustic signal into the lumen of the catheter. A receiving transducer (5) receives reflections of the acoustic signal from the lumen of the catheter. A low-frequency pressure transducer (42) senses the pressure in the lumen of the catheter and outputs a signal representing low-frequency pressure variations in the lumen. A signal-processing device (4, 6) receives and analyses the output signals from the receiving transducer (5) and the pressure transducer (42). Information can be obtained about the elasticity of the body cavity walls.

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## DEVICE AND METHOD FOR MEASURING IN BODY CAVITIES

### Background of the invention

5 The invention relates to the examination and measurement of passages and cavities in the human or animal body, and in particular of irregularities such as constrictions by means of a device comprising an electrical signal source, a catheter to be introduced into a cavity through a natural or surgically prepared opening in the body, a first transducer for transmitting an acoustic activation signal from the signal source to and through the catheter, a second  
10 transducer for reception of response signals from the catheter, and a computer for analysing the response signals in relation to the activation signal.

Various methods are known for the examination and measurement of occlusions, deformations, movements etc. in various human and animal cavities,  
15 e.g. airways such as the pharynx and the larynx, the gastro-intestinal tract, the urinary system, blood vessels etc.

US 5 823 965 discloses an apparatus and method for examining human or  
20 animal body cavities such as airways and the gastro-intestinal tract. The device has a flexible hose-like catheter, which is introduced into the cavity with the distal end of the catheter beyond the zone to be examined. An acoustical excitation signal is sent into the interior of the catheter. Irregularities reflect the acoustical signal, which is picked up by a receiving transducer and analysed.  
25 Such method is often referred to as reflectometric examination. A computer displays results of the examination on a screen. The device may comprise means for establishing a positive static pressure with the purpose of dilating the flexible wall of the measuring zone.

30 The purpose of the invention is to provide improvement in the measuring capability in such known devices.

## SUMMARY OF THE INVENTION

5 This purpose is achieved by means of the device of the invention. The provision of a pressure transducer adapted for obtaining low frequency pressure data from the cavity makes it possible to obtain these data simultaneously and hence make an analysis of the interaction of the corresponding different physical phenomena resulting in the different measurements.

10 The receiving transducer produces an output signal that is transmitted to the signal analysis device, e.g. a computer, where this is sampled together with the reflectometry data obtained from the reflectometry analysis.

15 The invention further relates to a method for obtaining dynamic data of the conditions in a body cavity, the method comprising obtaining reflectometric data on the shape of the body cavity and simultaneously obtaining values of low frequency pressure alterations in the body cavity.

20 After obtaining the data the method comprises transmitting the data obtained to a signal-processing device for simultaneous processing. Here the data obtained from the reflectometry and the low frequency may be used to provide corresponding area and pressure representations, e.g. in a coordinate system having pressure along one axis and area along another axis.

25 The low-frequency pressure signals can be the result of corresponding changes in the volume of the body cavity due e.g. to respiration or heartbeats, which are then reflected in the analysis of the signals received from the pressure transducer. Or the low-frequency pressure signals can be the result of low-frequency signals transmitted into the body cavity, in which case  
30 the received low-frequency signals represent the volume of the body cavity and thus also changes in the volume.

In preferred embodiments of the method, the cavity is an organic cavity, e.g. the respiratory passages, the blood or lymph tracts, the alimentary canal, or the urinary system or sections thereof of an animal or a human body. The invention also offers the possibility of making prostate or uterus examinations etc.

Other features and advantages of the present invention will become apparent from the following description of embodiments of the invention, which refers to the accompanying drawings.

#### **BRIEF DESCRIPTION OF THE DRAWINGS**

FIG. 1 shows a block diagram of the basic lay-out of the device according to the an embodiment of invention;

FIG. 2 is a perspective drawing of part of the catheter, at the location where the measurement is made;

FIG. 3 is a perspective drawing of part of the catheter in another embodiment of the invention;

FIG. 4 is a sectional view of the catheter according to FIG. 3 in a sectional plane at right angles to the axis of the catheter;

FIG. 5 illustrates the placing of a catheter in the upper airways of a patient being examined for tongue-fallback;

FIG. 6 illustrates the placing of a catheter in the upper airways of a patient being examined for stertorous respiration.

## DETAILED DESCRIPTION OF THE INVENTION

Figure 1 shows the basic layout of the device according to the invention. A catheter 1 has a proximal end A and a distal end B. The catheter 1 is for inserting, with its distal B end fist, through a natural or surgically prepared opening in a human or animal body. At its proximal end A, the catheter 1 is connected to auxiliary equipment, which is known per se and not illustrated, used for inserting the catheter in, e.g., the airways of a patient, through the mouth or the nostrils, or in the urinary system or an artery. After insertion the distal end B of the catheter will be in the cavity of the patient.

A controller 2 includes a signal generator that is adapted to give an activation signal to a transmitting transducer 3 connected to the catheter 1. The signal generator delivers the same signal to a signal analysis processor 4. An electro-acoustic receiving transducer 5 is connected to the catheter 1. When an excitation signal is transferred from the signal generator 2, the transducer 3 emits an acoustic signal that will propagate into the catheter. At the distal end of the catheter and at irregularities in the cross-section response signals are reflected and received by the transducer 5 and from there led to the signal analysis processor 4.

The system comprises a fluid pump 40 that is controlled by the controller 2 and connected to the proximal end A of the catheter through a tube 41. In the preferred embodiment the fluid is air. The pump 40 is capable of increasing the pressure in the catheter in a controlled manner, e.g. continuously or step-wise in small increments.

A pressure and flow control unit 42 comprises a static and low-frequency pressure transducer 5 for monitoring the pressure in the catheter 1, and a pressure release valve that opens at a predefined pressure and releases the pressure in the catheter to prevent overpressure. The pressure and flow con-

5      trol unit 42 may also comprise a flow control unit that detects and prevents an excessive flow of fluid in case of e.g. a ruptured catheter. Static and low-frequency pressure data from the pressure transducer is transmitted to the signal analysis processor 4 for processing and/or for display. In this context the term "low frequency" is intended to cover frequencies of physical move-ments that occur in human and animal physiological processes of normal and pathological nature. Thus, the pressure transducer preferably has an upper frequency limit of at least 10 - 100 Hz depending on the nature of the pro-cesses to be examined.

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Low-frequency acoustic signals may be generated by the controller 2 and used to excite the transmitting transducer 3 to transmit corresponding low-frequency signals into the body cavity, or the fluid pump can be used for generating such low-frequency signals superimposed on the fluid flow or static pressure generated by the pump. The low-frequency pressure trans-ducer 5 is used to sense the resulting low-frequency pressure, which then represents the volume and changes in volume of the body cavity.

20      The invention also relates to a method for obtaining dynamic data of the conditions in a body cavity, where the method comprises obtaining reflectometric data on the shape of the body cavity and simultaneously obtaining values of low frequency pressure alterations in the body cavity. After obtaining the data the method may comprise transmitting the data obtained to a signal-processing device for simultaneous processing. Here the data obtained from the reflectometry and the low frequency may be used to provide correspond-25      ing area and pressure representations, e.g. in a coordinate system having pressure along one axis and area along another axis.

30      The signal analysis processor 4 is connected to a computer 6 with a screen 7 by means of which it is possible to present an image, which e.g. graphically illustrates the results of the examination and measurements made.

The electro-acoustic transducer 3 can be of any suitable type known per se, e.g. an electromagnetic transducer, an electrostatic transducer, a piezo-electric transducer, etc. Its task is to transform the electronic signal from the signal generator 2 into an excitation signal in the interior of the catheter 1.

The electro-acoustic transducer 5 can also be of the above mentioned type, e.g. a microphone, the purpose of which is to receive an acoustic response signal from the distal end of the catheter and to transform this response signal into an electrical signal which is led to the signal analysis processor 4.

The electro-acoustic transducers 3 and 5 in figure 1 are preferably piezoelectric transducers or other reciprocal transducers, which in response to an electrical input signal emit an acoustic output signal, and in response to an acoustic input signal emit an electrical output signal. Instead of separate transmitting and receiving transducers 3 and 5 a single transducer can be used both as transmitter and receiver.

The analysis itself of the response signal in relation to the excitation signal belongs to a technique known per se.

A transducer 20 has been introduced from the outside through the outer chamber 12 and through the wall 15 so that the response signal receiving end 21 of the transducer 20 is located in the lumen 11.

25

FIG. 5 illustrates the use of the catheter in order to determine the position of and measure the so-called tongue fallback of a patient, e.g. the situation where the patient's tongue narrows the upper airways.



Here the catheter has been introduced through the nostrils and into the air passage. Part of the catheter is compressed by the rear end of the tongue in the zone D.

- 5 FIG. 6 illustrates the use of the catheter in order to determine the position of and measure the outbreak of vibrations in the soft palate (velum palatum).

FIG. 6 shows the situation illustrated in FIG. 5 as well as the situation where said soft parts of the palate compress the catheter in the zone E.

10

The mode of operation of the device according to the invention will be explained below.

- 15 In the prior art the sound signals may propagate not only in longitudinal modes but also in transversal modes, which will distort the measurements. This is the case e.g. in examinations of the airways and the lungs of a patient, the invention has the essential advantage that it is the inner cavity of the catheter which constitutes the measurement cavity proper, which can have local variations, e.g. at a constriction in the passage in which the catheter has been introduced. The catheter of the invention prevents the occurrence of transversal modes.
- 20

- FIG. 6 illustrates as already mentioned the situation where a patient is to be examined for vibrations in the soft parts of the palate, e.g. typically stertorous respiration. The vibrations in the zone E will influence at least one of the outer chambers of the catheter and the measurement equipment can carry out the positioning and measurement.
- 25

- Anatomical, physiological, surgical or other medical considerations may influence the choice of the inner and outer dimensions of the catheter and its
- 30

length, and the catheter may therefore be manufactured in different diameters and lengths.

5      Exact examinations of persons, whose airways are blocked during their sleep and who can be described as having stertorous respiration, are naturally very difficult and through the ages many failed corrective operations have been made on these patients.

10     This is the reason why equipment, which acoustically registers the stertorous respiration does not activate an alarm with sufficient security, as the non-occurrence of a "snoring sound" is either due to a quiet, steady respiration with a low regular flow, which is all right, or the airways being blocked for a long time. This is where the risk lies.

15     An internal measurement has the advantage that the patient is not awakened during the measurements by the excitation signal and at the same time the measurements are not influenced to a large extent by the high tone sound spectrum of the snoring sounds.

20     A correct "tightening" through the nose happens automatically due to the reflexory swallowing, and a connection (transducer/microphone part) at the end which projects out of the nose can be made without problems.

25     It should also be noted that the measurement equipment (hardware/software), which adequately makes the measurements in each chamber and during measurements changes the static pressure in each chamber can also concurrently give information about the elasticity of the tissue giving counter-pressure to the surface of the chambers.

30     By establishing a static pressure in the catheter and superimposing acoustic signals with frequencies ranging from static pressure (infrasound) up to e.g.

200 Hz in the lumen and the chambers, and combining this low-frequency sound signal with the acoustic reflectometric measurements, such as described in US 5 823 965, it is possible also to obtain valuable information about the elasticity in the walls to which the catheter wall establishes a contact during the various pressure conditions.

**CLAIMS**

1. A device for examining human and animal body cavities, the device comprising

5

- a catheter (1) with a proximal end (A) and a closed distal end (B) for inserting into the human or animal body cavity, the catheter having a lumen extending from the proximal end into the catheter,

10 - a signal generator (2) for generating an excitation signal,

- a transmitting transducer (3) coupled to receive the excitation signal and arranged to transmit, in response to the excitation signal, a corresponding acoustic signal into the lumen of the catheter,

15

- a receiving transducer (5) arranged to receive reflections of the acoustic signal from the lumen of the catheter,

20 - a pressure transducer (42) sensitive to low frequencies and arranged to sense, when inserted into the body cavity, the pressure in the lumen of the catheter and outputting a signal representing low-frequency pressure variations, and

25 - a signal processing device (4, 6) for receiving and analysing the output signals from the receiving transducer (5) and the pressure transducer (42).

2. A device according to claim 1 wherein the excitation signal comprises an impulse signal of duration short enough to make the corresponding reflected signal distinguishable from the excitation signal.

30

3. A device according to claim 1, where the pressure transducer (42) is sensitive to frequencies up to at least 10 Hz, preferably up to at least 100 Hz.

4. A method for obtaining dynamic data of the conditions in a human or animal body cavity, the method comprising

- transmitting an acoustic impulse signal into the body cavity,

- receiving reflections of the acoustic impulse signal from the body cavity,

- obtaining data of low frequency pressure changes in the body cavity, and

- analysing the received reflections and the data of low frequency pressure changes to obtain information on the body cavity.

5. A method according to claim 4 comprising transmitting the data obtained to a signal processing device for simultaneous processing.

6. A method according to claim 4, wherein the analysis of the received reflections and of the data of low frequency pressure changes are used to provide corresponding area and pressure representations.

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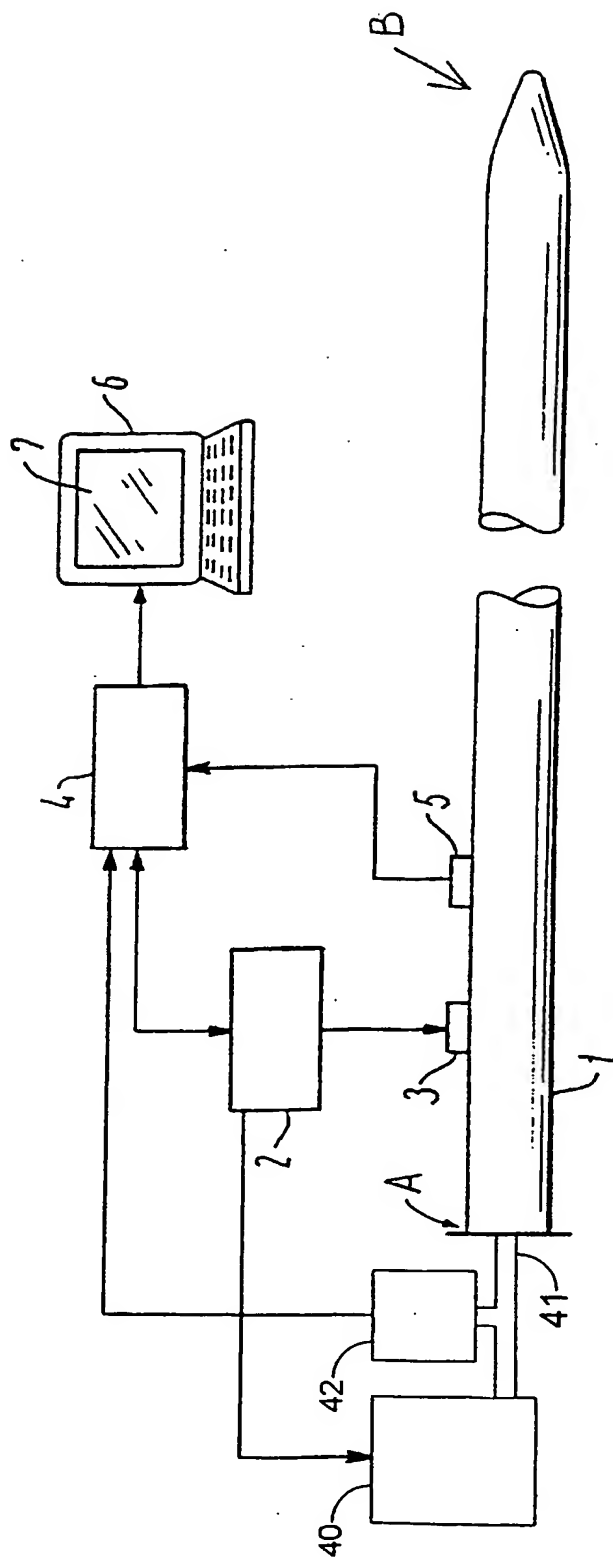


FIG. 1

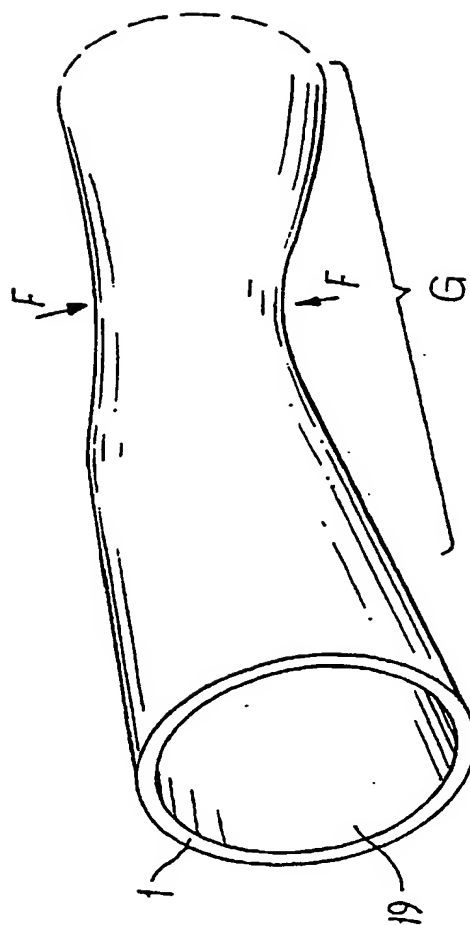


FIG. 2

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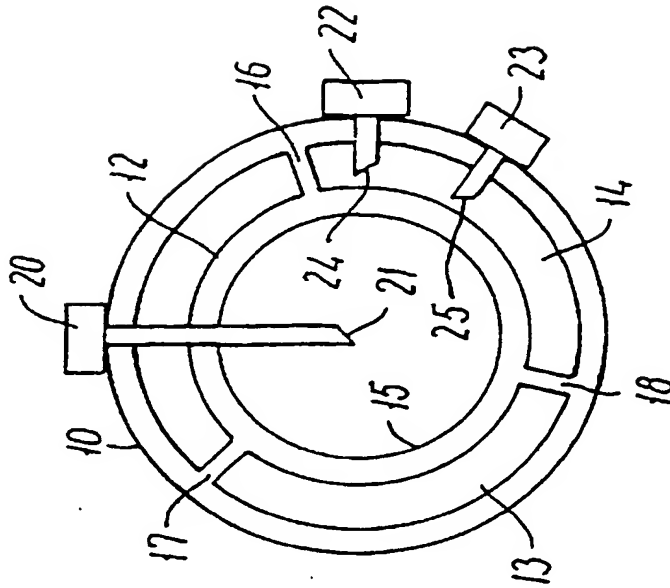


FIG. 4

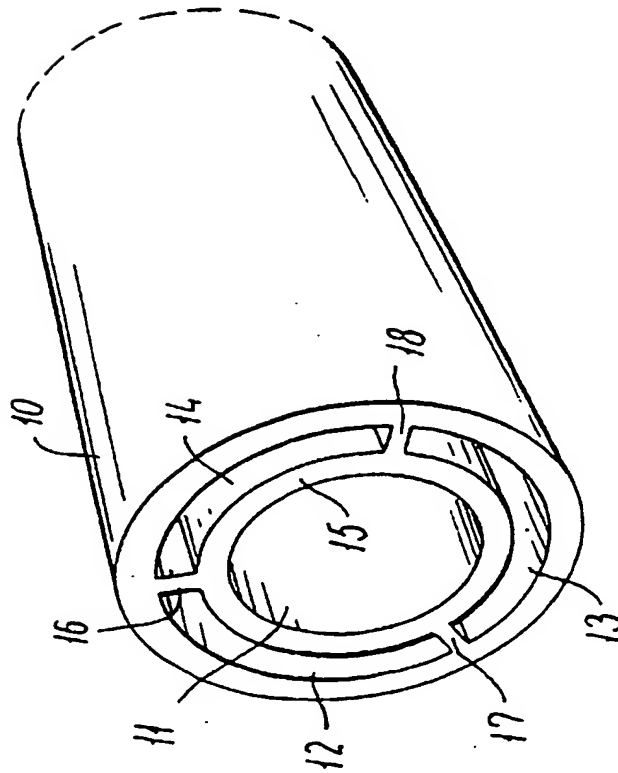


FIG. 3

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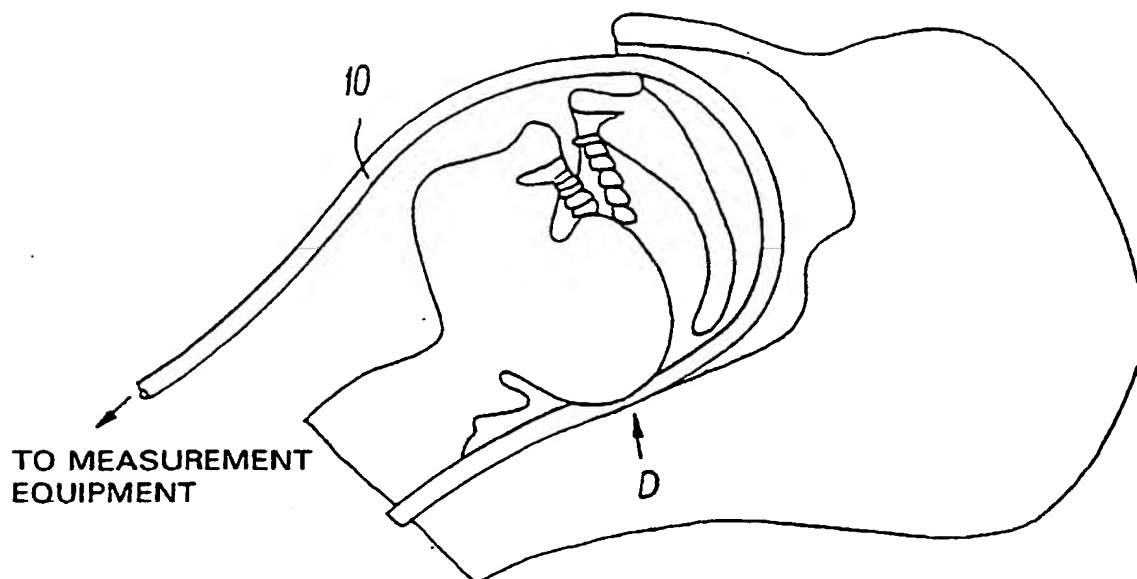


FIG. 5

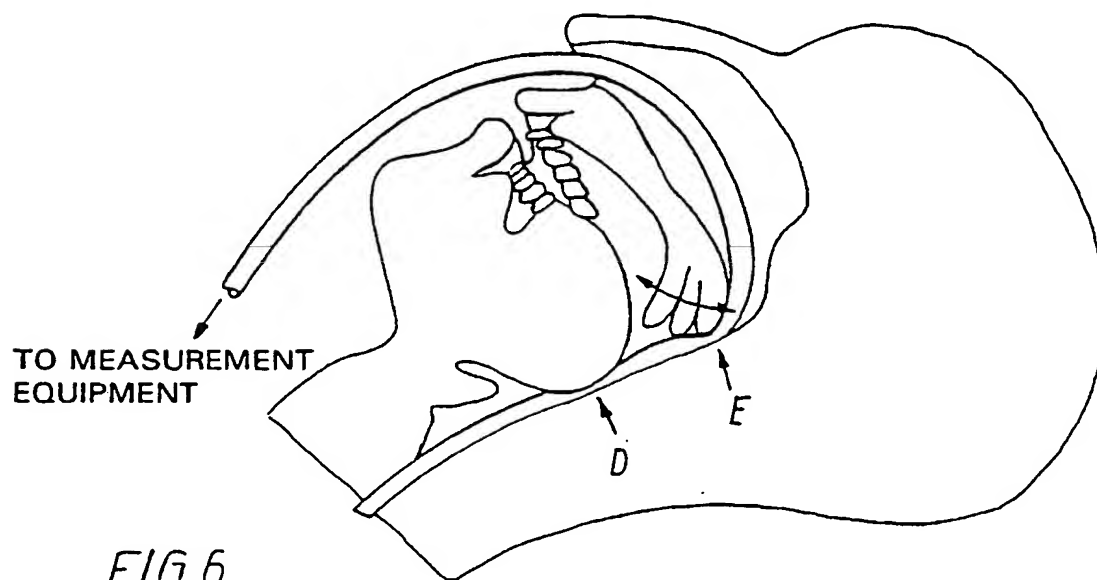


FIG. 6

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# INTERNATIONAL SEARCH REPORT

International Application No. PCT/DK 03/00792

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.1

Claims Nos.: 4-6

Claims 4-6 relate to a method of treatment of the human body by surgery or by therapy/a diagnostic method practised on the human or animal body/Rule 39.1(iv). Nevertheless, a search has been executed for these claims. The search has been based on the alleged effects of the compound(s)/product/device.

# INTERNATIONAL SEARCH REPORT

International Application No

PCT/03/00792

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# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/DK 03/00792

## Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 4-6  
because they relate to subject matter not required to be searched by this Authority, namely:  
see FURTHER INFORMATION sheet PCT/ISA/210
2. ☐ Claims Nos.:  
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

# INTERNATIONAL SEARCH REPORT

International Application No

PCT/EP 03/00792

**A. CLASSIFICATION OF SUBJECT MATTER**  
IPC 7 A61B5/0215 A61B8/12

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61B A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ, INSPEC

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 882 314 A (LOUIS BRUNO ET AL) 16 March 1999 (1999-03-16) column 1, line 33 -column 2, line 4 column 2, line 37 -column 3, line 16 abstract; claims 1,12; figure 1 ---	1-6
A	US 5 573 007 A (BOBO SR DONALD E) 12 November 1996 (1996-11-12) the whole document ---	1-6
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☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

### \* Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

- "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- "&" document member of the same patent family

Date of the actual completion of the international search

9 March 2004

Date of mailing of the international search report

07.04.2004

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